

## REMARKS

Clean copies of the amendment to the specification and of all claims remaining in this application after entry of these amendments are submitted herewith.

The Examiner rejected claims 1-12 under 35 U. S. C. § 112, second paragraph. The Examiner takes the position that claims 1-12 claim subject matter which was not disclosed in the application as filed. Specifically, the Examiner objects to the recitation in the claims of “a topical fluid silicone gel not released from silicone gel sheeting.” However, the application as filed identified the enabling silicone as “[a] polysiloxane derivative [ ] marketed under the trade name Kelo-cote.” The Kelo-Cote website, <http://www.kelocote.com/>, identifies Kelo-Cote brand polysiloxane derivative as described in U. S. Patent 5,741,509, which coincidentally is of record in this application. That information has been added to the previous identification in the application of the topical fluid silicone as Kelo-cote brand polysiloxane derivative. Accordingly, the 35 U. S. C. § 112, second paragraph rejection is overcome.

The Examiner rejected claims 1 and 2 under 35 U. S. C. § 102. The Examiner relied upon Kushner U. S. Patent 5,741,509 (hereinafter Kushner) to support this rejection. Claim 1 has now been amended to incorporate the limitations of prior claim 3. Kushner neither discloses nor suggests the desirability of alternately applying a topical fluid silicone not released from silicone gel sheeting to the scar, and applying silicone gel sheeting to the scar, as now specifically recited in claim 1. Accordingly, the 35 U. S. C. § 102 rejection of claim 1, and claim 2 which depends from claim 1, is overcome.

The Examiner rejected claims 4-12 under 35 U. S. C. § 103. The Examiner relied upon the combination of Kushner, Lee U. S. Patent 5,552,162 (hereinafter Lee) and Tankovich U. S. Patent 5,897,549 (hereinafter Tankovich) to support this rejection. The Examiner relies upon Kushner to disclose the application of fluid silicone in the treatment of hypertrophic and keloid scars, Lee to teach the use of silicone-based gels and X-ray irradiation, and Tankovich to teach substitution of a laser for Lee’s X-radiation.

When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) (“the central question is whether there is reason to combine [the] references,” a question of fact drawing on the Graham factors).

“The factual inquiry whether to combine references must be

thorough and searching.” Id. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) (“a showing of a suggestion, teaching, or motivation to combine the prior art references is an ‘essential component of an obviousness holding’”) (quoting C.R. Bard, Inc., v. M3 Systems, Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998)); In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (“Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”); In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (“teachings of references can be combined only if there is some suggestion or incentive to do so.”) (emphasis in original) (quoting ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

The need for specificity pervades this authority. See, e.g., In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (“particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”); In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) (“even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.”); In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination “only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references”).

2. With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that “the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software” and that “another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial” do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and

wrong application

could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to “[use] that which the inventor taught against its teacher.” W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion.

Deferential judicial review under the Administrative Procedure Act does not relieve the agency of its obligation to develop an evidentiary basis for its findings. To the contrary, the Administrative Procedure Act reinforces this obligation. See, e.g., Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 43 (1983) (“the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'”) (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)); Securities & Exchange Comm'n v. Chenery Corp., 318 U.S. 80, 94 (1943) (“The orderly function of the process of review requires that the grounds upon which the administrative agency acted are clearly disclosed and adequately sustained.”).

In its decision on Lee's patent application, the Board rejected the need for “any specific hint or suggestion in a particular reference” to support the combination of the Nortrup and Thunderchopper references. Omission of a relevant factor required by precedent is both legal error and arbitrary agency action. See Motor Vehicle Manufacturers, 463 U.S. at 43 (“an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem”); Mullins v. Department of Energy, 50 F.3d 990, 992 (Fed. Cir. 1995) (“It is well established that agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action.”). As discussed in National Labor Relations Bd. v. Ashkenazy Property Mgt. Corp., 817 F.2d 74, 75 (9th Cir. 1987), an agency is “not free to refuse to follow circuit precedent.”

The foundation of the principle of judicial deference to the rulings of agency tribunals is that the tribunal has specialized knowledge and expertise, such that when reasoned findings are made, a reviewing court may confidently defer to the agency's application of its knowledge in its area of expertise. Reasoned findings are critical to the performance of agency functions and judicial reliance on agency competence. See Baltimore and Ohio R. R. Co. v. Aberdeen & Rockfish R. R. Co., 393 U.S. 87, 91-92 (1968) (absent reasoned findings based on substantial evidence effective review would become lost “in the haze of so-called expertise”). The “common knowledge and common sense” on which the Board

relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in Zurko, 258 F.3d at 1385, 59 USPQ2d at 1697, that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.'" The Board's findings must extend to all material facts and must be documented on the record, lest the "haze of so-called expertise" acquire insulation from accountability. "Common knowledge and common sense," even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority. See Allentown Mack, 522 U.S. at 376 ("Because reasoned decisionmaking demands it, and because the systemic consequences of any other approach are unacceptable, the Board must be required to apply in fact the clearly understood legal standards that it enunciates in principle . . . .")

The case on which the Board relies for its departure from precedent, In re Bozek, 416 F.2d 1385, 163 USPQ 545 (CCPA 1969), indeed mentions "common knowledge and common sense," the CCPA stating that the phrase was used by the Solicitor to support the Board's conclusion of obviousness based on evidence in the prior art. Bozek did not hold that common knowledge and common sense are a substitute for evidence, but only that they may be applied to analysis of the evidence. Bozek did not hold that objective analysis, proper authority, and reasoned findings can be omitted from Board decisions. Nor does Bozek, after thirty-two years of isolation, outweigh the dozens of rulings of the Federal Circuit and the Court of Customs and Patent Appeals that determination of patentability must be based on evidence. This court has remarked, in Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1421 (Fed. Cir. 1999), that Bozek's reference to common knowledge "does not in and of itself make it so" absent evidence of such knowledge.

In re Lee, 61 U. S. P. Q. 2d 1430, 1433-1435, (Fed. Cir. Jan. 18, 2002).

Under Lee, in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See M.P.E.P. Section 2143 - Section 2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). It appears that the Examiner intends to present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of Kushner, Lee and Tankovich. However, Lee does not discuss the application of fluid silicone gel, such as the Kelo-Cote fluid silicone gel specifically identified in this application, its immediate parent, and grandparent provisional application, to a scar. The teaching of Lee is specifically recognized in the background of the present application, for example, at page 3, lines 12-16: "A variety of treatments for hypertrophic scars and keloids have been advocated in the past. These include \* \* \* silicone gel sheeting \* \* \* ." With respect to Lee's teaching of the use of X-ray irradiation in the treatment of hypertrophic and keloid scars, Lee quite clearly teaches away from the use of such radiation in the treatment of scars:

"Existing therapy for hypertrophic scars and keloids includes surgery, mechanical pressure, steroids, x-ray irradiation and cryotherapy. There are many disadvantages associated with each of these methods. Surgical removal of the scar tissue is often incomplete and can result in the development of hypertrophic scars and keloids at the incision and suture points. Steroid treatments are unpredictable and often result in depigmentation of the skin. *X-ray therapy is the only predictably effective treatment to date; however, because of its potential for causing cancer, it is not generally recommended or accepted.*" Lee, col. 4, lines 54-64, emphasis Applicant's.

Tankovich neither discloses nor suggest the desirability of combining laser therapy with the use of topical fluid silicone not released from silicone gel sheeting. Tankovich neither discloses nor suggest the desirability of substituting laser therapy for hypertrophic scars for Lee's X-ray therapy for hypertrophic scars.

Thus, there is no disclosure or suggestion of the desirability of combining any element or combination of elements from Kushner with any element or combination of elements from Lee, and no disclosure or suggestion of the desirability of combining any element or combination of elements from Lee with any element or combination of elements from Tankovich. The first prong of the test for *prima facie* obviousness is not met.

The Examiner also cited U. S. Patents 6,503,246 and 6,572,878 as of interest. Applicant has considered these references and believes his claims are patentable over them. Accordingly, Applicant submits that his claims 1, 2 and 4-12, as amended herein, are entitled to favorable consideration, culminating in allowance. Such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees which may be due to render this response a timely response to the June 17, 2003 official action, to Applicant's undersigned counsel's deposit account 10-0435 with reference to file 6631-27092. A duplicate copy of this authorization is enclosed for this purpose.

Respectfully submitted

A handwritten signature in black ink, appearing to read "Richard D. Conard", written in a cursive style.

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